DH, MMRegulations

From: DH, MedMarijuana
Sent: Wednesday, April 7, 2021 10:10 AM
To: DH, MMRegulations
Subject: FW: [External] Comments and suggestions
Attachments: MLEE comments for Proposed Rule DOH PA MMJ v3.pdf

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From: Marci Lee <marcilee@gmail.com>
Sent: Sunday, April 4, 2021 3:40 PM
To: DH, MedMarijuana <RA-DHMEDMARIJUANA@pa.gov>
Cc: Marci Lee <marcilee@gmail.com>
Subject: [External] Comments and suggestions

Please see the attached file for the comments for the rules and regulations.

Thank you for all the hard work and effort to create our PA program.

Many thanks,

Marci

RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1230]

Medical Marijuana; Practice and Procedure; Temporary Regulations

[48 Pa.B. 2814]
[Saturday, May 12, 2018]

The Department of Health (Department) is publishing temporary regulations in Chapter 1230 (relating to practice and procedure—temporary regulations) to read as set forth in Annex A. These temporary regulations are published under the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110). Section 1107 of the act (35 P.S. § 10231.1107) specifically provides that, to facilitate the prompt implementation of the act, the Department may promulgate temporary regulations that are not subject to sections 201—205 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201—1205), known as the Commonwealth Documents Law, the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P.S. §§ 732-204(b) and 732-301(10)).

To implement the Medical Marijuana Program, the Department periodically published temporary regulations regarding various sections of the act. The temporary regulations for practice and procedure will expire on May 12, 2020.

Chapter 1230 pertains to growers/processors, dispensaries, laboratories, disappointed medical marijuana organization permit applicants and any other person choosing to challenge an action taken by the Office of Medical Marijuana under the act.

Interested persons are invited to submit written comments, suggestions or objections regarding these temporary regulations to John J. Collins, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120, (717) 547-3047, RA-DHMedMarijuana@pa.gov.

Code	Text	Comment
§ 1141a.46. Reports	*§ 1141a.46. Reports* This proposed section largely mirrors the current § 1141.46 (relating to reports), except for proposed revisions to subsection (a), as detailed as follows. *Subsection (a).* This proposed subsection outlines the ongoing reports medical marijuana organizations must provide to the Department and details the required contents of the reports. Proposed revisions to subsection (a)(1) and (2) require dispensaries and growers/processors to report the "average price per unit of medical marijuana products sold" rather than the "per-dose price." These revisions are necessary because a "dose" varies from one patient to another and from one product to another.	**Comment: There is uniformity with the unit sizes in some forms of cannabis in our program (i.e., flower is 1 gram, 3.5 g or 7g and cartridges are 500 mg or 1 gram etc.).** **However, the tinctures and solutions vary in mL per bottle. We have 12.5 mL, 15 mL and 30 mL bottles so far.** **We need to know the mg/mL and mg per bottle.** **The ingested forms may vary in number of capsules or tablets or softgels per bottle. The growers will vary in expression of cannabinoids per capsule too. It is most helpful to see each cannabinoids mg per capsule and not add them together, which can be misleading. For example, if a capsule has 5 mg THC and 5 mg CBD, it is not helpful to label it as a 10 mg capsule. Each cannabinoid should be listed separately.**
§ 1141a.48. Training	*§ 1141a.48. Training* This proposed section further provides that the Department will make its training course available at no cost to medical marijuana organizations, and medical marijuana organizations must retain the attendance records for the training and make them available to the Department upon request.	**Comment: When I took this training in 2019, there was some outdated information and the training did not reflect updated certifying conditions etc. the "TRAIN" training may need to be updated on a regular basis.** **Comment: "attendance records" implies in-person training to me. I remember the training was online and I shared the certificate of completion with my supervisors.**
§ 1151a.34. Packaging and labeling of medical marijuana products	*§ 1151a.34. Packaging and labeling of medical marijuana products* *Subsection (d).* This proposed subsection requires that all packaging and labeling be approved by the Department and sets out the information that must be included on each label. The Department proposes to expand upon the requirements in the current subsection (d) by: (1) requiring that all packaging receive prior written approval of	**Comment: we have some tinctures and solutions that only label the carton/outer packaging and the containers (Bottles) are unlabled. This will be safer for patients that often discard the cartons to know the mg/mL of each cannabinoid and terpenes for each batch.** **Comment: The standardization of the ratio expression is a step in the direction of simplifying the labels to improve the ability of the patient to understand what he/she is taking. I suspect there will be push back here since we have growers in PA listing the**

	the Department; (2) requiring labels to list the species and percentages of all cannabinoids and individual terpenes; (3) requiring that labels be firmly affixed to the container directly holding medical marijuana as well as outer packaging; and (4) requiring that THC be the first number in a THC:CBD ratio, when the labeling includes a ratio. These revisions minimize patient confusion caused by medical marijuana packaging, and also ensure that individuals and law enforcement officials can readily determine if a medical marijuana product was purchased at a dispensary. This proposed subsection otherwise mirrors the current subsection (d), except for technical revision to subsection (d)(2) to correct syntax.	**ratio in various ways.** **Comment: In the realm of prescription medications, we know that health care professionals struggle with calculating doses in general and especially when the math involves ratios and percentages to express concentration. Many people in our program do not understand that 1:1 does not mean weak or strong and that 8:1 does not mean it is stronger than 1:1. In the examples of epinephrine (and other medications), we have many medication error reports that resulted in the phasing out of the expression of concentration at the level of the USP as a ratio to decrease confusion in 2016. The USP is the standard setting organization for the pharmaceutical industry.** **https://www.usp.org/health-quality-safety/medication-safety-labeling/elimination-ratio-expression single-entity-drug-labels** **Comment: instead of wasting time discussing which cannabinoid to list first in the ratios, we may simply list the mg/mL of each cannabinoid and mg/total bottle size of each cannabinoid to make that information as clear as possible for all the people that need to interpret the information for dosing.** **At this time our growers are individually listing a dose volume on the labels of the cartons and this is also not standardized. Some growers one dose is 0.5 mL and others are using 0.25 mL. If we select a standard way of expressing the concentration in terms of mg/mL, that may be the safest option moving forward.**
§ 1151a.42. Complaints about or recall of medical marijuana products	*§ 1151a.42. Complaints about or recall of medical marijuana products* This proposed section mirrors the current § 1151.42 (relating to complaints about or recall of medical marijuana products), with two exceptions, as detailed as follows. This proposed section provides that in the event of a complaint of an adverse event from using medical marijuana, a dispensary must notify the Department and the grower/processor from which it purchased the medical marijuana	**Comment: Does this mean <u>every</u> adverse event or do we want to specify or define a serious adverse event for this section. We advise patients on dosing and to decrease doses when side effects are occurring and the determination that there may be a product problem in these examples is rarely a concern.**

	and outlines the grower/processor's subsequent investigatory and reporting obligations. Further, this proposed section addresses processes and procedures in the event of a voluntary or mandatory recall of medical marijuana or medical marijuana products, subject to penalties for noncompliance; specifies the information that must be entered into the electronic tracking system; and specifies the requirements of a recall plan.	
§ 1161a.23. Dispensing medical marijuana products	*§ 1161a.23. Dispensing medical marijuana products* This proposed section mirrors the current § 1161.23 (relating to dispensing medical marijuana products). This proposed section provides that a dispensary may only dispense to individuals who present a valid identification card; specifies the necessary prerequisites the dispensary must complete before dispensing medical marijuana products and before completing a transaction, including information that must be listed on a receipt and recordkeeping requirements.	**Comment: there is confusion around this for me. Some dispensaries require you to show a PA ID and PA Patient card before entering the dispensary and others may on ask for the PA Patient card.** **QUESTION: In this proposed regulation, is the PA Patient card considered a valid ID card?**
§ 1161a.24. Limitations on dispensing	*§ 1161a.24. Limitations on dispensing* This proposed section mirrors the current § 1161.24 (relating to limitations on dispensing). This proposed section provides that a dispensary may only dispense medical marijuana or medical marijuana in a quantity or form provided for on the patient's certification and permitted by the act or these proposed regulations. This proposed section also prohibits a dispensary from dispensing more than a 30-day supply of medical marijuana to a patient and not before the patient has exhausted all but a 7-day supply of medical marijuana.	**Comment: does this mean based on if the certifying doctor lists any restricted forms or based on the certifying condition?** **It is challenging to interpret the check boxes next to some forms since those are not in alignment with the names of the forms on the dispensary menus.** **Comment: it is hard for wellness associate staff to estimate if a patient has more than a 7-day supply left of medicine at home.** **Similar to prescription medications, there are forms of cannabis that may be used for maintenance of chronic conditions and daily or more than once daily. We also have some "as needed" cannabis medications that may last longer depending on how often they are used per month.**
§ 1161a.25. Licensed medical professionals at	*§ 1161a.25. Licensed medical professionals at facility* This proposed section mirrors the current	**Comment: see also 1181a.32 DOH will provide a list of approved training providers for CE programs for medical professionals.**

facility	§ 1161.25 (relating to licensed medical professionals at facility), with one addition, as detailed as follows. This proposed section provides that a physician or pharmacist must be present at the facility during operating hours and, if a permittee operates more than one facility under the same permit, a physician assistant or certified nurse practitioner may cover the other sites. Further, this proposed section provides training requirements and continuing education standards for physicians, pharmacists, physician assistants and certified nurse practitioners. This section also prohibits a practitioner or physician from issuing patient certifications while at the facility.	
§ 1161a.27. Items and services provided at a dispensary	*§ 1161a.27. Items and services provided at a dispensary* *… Subsection (d).* Aside from revising one citation to refer to proposed Chapter 1151a (relating to growers/processors), this proposed subsection mirrors the current subsection (d). This proposed subsection provides that dispensaries may dispense a medical marijuana product with a THC concentration of less than 0.3% if purchased from a grower/processor that has obtained prior Department approval. *… Subsection (e).* This proposed subsection delineates prohibited actions for a dispensary. Specifically, dispensaries may not (1) provide medical marijuana product at no cost unless the patient is approved for financial assistance by the Department; (2) make purchases conditional upon the patient purchasing a medical device at the facility or a separate facility; (3) deliver, or contract with a third party to deliver medical marijuana; and (4) sell items and services unrelated to the use of medical marijuana products. This proposed subsection removes the current prohibition on advertising activities, as that provision caused confusion. The removal of this subsection does not, however, negate the general requirement in proposed §	**Question: Does this mean that dispensaries in PA can sell hemp-based CBD products inside the dispensary? Can the growers of the hemp-based CBD products be based or located outside of PA?** **Question: Is the intent of this proposed regulation meaning for the grower processors of the Medical cannabis in PA to also offer hemp-based CBD products in PA that may be sold in the dispensary?** **Comment: I cannot tell if this means that dispensary employees are not allowed to become caregivers for patients. I cannot tell if this means that caregiver volunteers are not permitted (e.g., Soulful Cannabis). Soulful Cannabis connects volunteers directly with patients that may still be waiting for a family member to get their Caregiver card, which can take awhile.**

	1141a.50(b) (relating to advertising by a medical marijuana organization) that all promotional, advertising and marketing materials must be approved by the Department prior to use. Further, this proposed subsection revises the prohibition on delivering medical marijuana products by prohibiting a dispensary from contracting delivery to third parties, in addition to prohibiting a dispensary from delivering to a patient or caregiver, and by adding a prohibition on the sale of items unrelated to the use of medical marijuana. These revisions seek to limit the services a dispensary may provide to a patient or caregiver that are unrelated to the sale of medical marijuana products.	
§ 1161a.28. Labels and safety inserts	*§ 1161a.28. Labels and safety inserts* … Compared to the requirements in current § 1161.28, this proposed section adds the requirements that that all cannabinoids and terpenes and corresponding percentages be listed on the label and that a label be firmly affixed to a container directly holding medical marijuana.	**Comment: it may be challenging to list ALL the terpenes on the container labels. There are 100s of terpenes in cannabis medicines. Consider revise to require growers to list the top 5 terpenes or other agreed upon number of terpenes on the container labels. In pharmaceuticals, the container is the part of the package that is in direct contact with the medicine. The carton is the packaging that houses a container. Safest is for the container to be adequately labeled.** **Comment: at this time we have multiple growers with multiple forms listing this on the carton but not the containers. By doing this, the result is that patients may have unlabeled containers of cannabis medicines at home. This may make it difficult to administer and adjust the dosing of the medicines as needed.** **Comment: for some ingested forms, we prefer to also have the milligrams of the cannabinoids per mL (or per capsule) and per container.**
§ 1161a.30. Access to dispensary	*§ 1161a.30. Access to dispensary facilities*	**Question: I am not sure how this was worded before. Are firefighters included in this too? Are firefighters local government officials?**

facilities	*… Subsection (f).* Proposed subsection (f) mirrors the current subsection (f). This proposed subsection provides that nothing in proposed § 1161a.30 will limit the right of the Department or its authorized agents, or State or local law enforcement or other Federal, State or local government officials from entering any area of a grower/processor site or facility, if entrance is necessary to perform their functions and duties that pertain to the act or this proposed part.	
§ 1161a.38. Complaints about or recall of medical marijuana products	*§ 1161a.38. Complaints about or recall of medical marijuana products* This proposed section mirrors the current § 1161.38 (relating to complaints about or recall of medical marijuana products), except for revising a citation to refer to proposed Chapter 1151a. This proposed section provides that dispensaries must notify the Department and the grower/processor from which it purchased the medical marijuana product immediately upon becoming aware of a complaint made to the dispensary by an individual who experienced an adverse event resulting from interaction with a medical marijuana product. If the grower/processor were to recall the product, the dispensary is required to cease dispensing the item in question and coordinate a return of the recalled product.	**Question: is the why for this regulation to discover a product problem? "immediately" notify DOH and GP for all complaints of an adverse event with medical cannabis. Again I suspect, we may want to define a serious adverse event vs every time a patient calls to ask for help with dosing or has taken a cannabis medicines with a prescription medication that caused side effects.** **NCCMERP categories for medication error events in prescription drug realm.** https://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf https://www.nccmerp.org/
§ 1171a.25. Renewal of an approval issued to a laboratory	*§ 1171a.25. Renewal of an approval issued to a laboratory* This proposed section mirrors the current § 1171.25 (relating to renewal of an approval issued to a laboratory), except for revising a citation to refer to this proposed chapter. This proposed section provides the timeframe in which an approved laboratory must submit an application for renewal.	**Questions:** **How frequently do the labs need to submit for renewal?** **How many labs will a GP typically use on a regular basis?**
§ 1171a.29. Testing requirements	*§ 1171a.29. Testing requirements* *Subsection (g).* This proposed subsection (g) specifies	**Comments: and may be a typo.** **Question: why are GP requesting additional testing prior to harvesting? And why don't those additional tests have to be entered**

	tracking and disposal requirements. Where the current subsection (g) requires that all tests be entered into the electronic tracking system, this proposed subsection (g) provides that only testing performed on samples of harvest lots and process lots must be entered into the electronic tracking system, which and allows for additional tests to be performed without being entered into the electronic tracking system. Many permittees have requested the ability to conduct additional testing prior to harvesting. Additionally, a citation has been amended to refer to this proposed chapter and the proposed Chapter 1151a.	**into the electronic tracking system?**
§ 1171a.35. Laboratory reporting	*§ 1171a.35. Laboratory reporting* The Department proposed to make several changes to the current § 1171.35 (relating to laboratory reporting), as detailed as follows. *…Subsection (b).* This proposed subsection provides that an approved laboratory maintain a certificate of analysis for 4 years and amends the current subsection to include those test results not required to be entered into the electronic tracking system. Additionally, proposed amendments to this subsection add paragraph (1), which requires an approved laboratory to immediately provide to the Department an electronic copy of a certificate of analysis for those test results that are not required to be entered into the electronic tracking system, and paragraph (2), which modifies the current subsection (b) to apply only to results entered into the electronic tracking system.	**Comments: I am confused here. Consider clarification.**
§ 1171a.36. Advertising.	*§ 1171a.36. Advertising.* This proposed section mirrors the current § 1171.36 (relating to advertising). This proposed section prohibits a laboratory from advertising or promoting its services to the general public. This proposed section clarifies that personal solicitation by a laboratory employee is considered advertising or promotional marketing. It also provides that a laboratory may only advertise to a grower/processor those services performed on site, subject to	**Question: Does this mean that only the GP may call the lab. If a lab employee called the GP, it is considered advertising.** **Consider clarification of this section.**

	prior Department approval. Further, this proposed section provides that a laboratory may erect signage at its facility, subject to compliance with local zoning requirements and this proposed section.	
§ 1181a.23. Medical professionals generally	*§ 1181a.23. Medical professionals generally* This proposed section mirrors the current § 1181.23 (relating to medical professionals generally), except for revising a citation in subsection (b) to refer to this proposed chapter. This proposed section provides that, like the requirements for a registered practitioner, the requirements to be a registered medical professional are an ongoing responsibility to maintain. The proposed section also provides that a medical professional may not assume any duties at a dispensary until all requirements are satisfied. This proposed section further requires that a medical professional notify the practitioner listed on the patient certification of any adverse reaction suffered by the patient as a result of interaction with a medical marijuana product purchased at the dispensary.	**Comment: "any adverse reaction" vs a serious adverse reaction?** **Cannabis is generally very safe and has a wide safety profiles resulting a wide range of safe and effective doses that do not cause adverse reactions.** **Comment: the practitioner that certifies the patient is not commonly involved in the other aspects of the medical management of a particular patient. Pharmacist in this proposed regulation is required to notify the certifying doctor of adverse reaction.** **More appropriate may be to assist the patient as needed (and with the patient's permission) in communicating details of regimen to their actual primary care or other doctor involved in the management of their medical conditions.**
§ 1181a.24. Physician registration	*§ 1181a.24. Physician registration*	**Question: is the certifying doctor required to be based in PA?** **Comment: I have noticed some addresses outside of PA and with non-PA zip codes when I am verifying certifications.**
§ 1181a.28. Modifying a patient certification	*§ 1181a.28. Modifying a patient certification* This proposed section mirrors the current § 1181.28 (relating to modifying a patient certification). This proposed section provides that a practitioner may not modify the form of medical marijuana products specified on a patient certification for 30 days from the date the receipt is entered into the electronic tracking system unless the practitioner notifies the Department. This proposed section also requires a practitioner to provide a copy of a modified patient certification to the patient or the patient's	**Comment: I would like to understand the why on this proposed regulation. There seems to be no need for copies of this to be provided since it is available to all on the website electronically. This applies to 1181a.27 too.** **We saw an uptick in Dr listing no inhaled forms when pandemic started and that was by mistake. In order to modify this as not a firm restriction for that individual patient and more of a general recommendation, the Dr would have to wait 30 days to make any changes to the certification. I am not sure I understand why there is a 30-day**

	caregiver and to the Department, as well as to retain a copy in the patient's file.	**waiting period.**
§ 1181a.31. Practitioner prohibitions	*§ 1181a.31. Practitioner prohibitions* This proposed section mirrors the current § 1181.31 (relating to practitioner prohibitions), except for adding subsection (g). This proposed section lists the prohibitions for practitioners, including: (1) accepting any form of remuneration for issuing patient certifications other than a fee for the patient consultation; (2) holding a direct or economic interest in a medical marijuana organization; (3) advertising as a certifying physician; (4) issuing a patient certification for personal use or for a family or household member; (5) acting as a caregiver for a patient certified by the practitioner; and (6) receiving or providing medical marijuana samples. In addition, proposed subsection (g) prohibits a practitioner from charging patients excessive fees. The Department is proposing the change due to patient complaints of practitioners taking advantage of the certification process by charging excessive lab testing, follow-up, or other fees not initially disclosed. Section 301(a)(11) of the act (35 P.S. § 10231.301(a)(11)) provides that the Department "shall collaborate as necessary with other Commonwealth agencies or contract with third parties as necessary to carry out the provisions of this act." The Department will collaborate with the Department of State (DOS), which licenses physicians, and refer for investigation complaints that a practitioner is engaging in unscrupulous billing practices. The DOS will investigate and, if the DOS finds a violation of the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.51a), or the Osteopathic Medical Practice Act (63 P.S. §§ 271.1—271.18), the DOS will impose sanctions. If the DOS suspends, revokes, limits or otherwise restricts the practitioner's license, the practitioner will be removed from the medical marijuana physician registry under proposed § 1181a.26(a).	**Comment: this is a problem we have seen on occasion. One psychiatrist has been charging patients almost $400 for a three month certification and requiring follow up visits.** **In some cases when a Dr is also seeing a patient for another reason, I have heard of them waiving the fee completely. In this case, the doctor is setting the patient up for 4 certifications and fee per year instead of authorizing a 12 month certification for one fee per year. Patients are upset.** **I have heard one instance of a patient getting invited for atypical follow up and I think labwork was a part of that as well.** **Most commonly we see a certification for one year and no restrictions and the doctor is not the patient's doctor for any other reason than the certification.** **Comment: there is another practice that authorizes less than one year certifications and it appears that the patients may or may not be in the practice for other purposes.**
§ 1181a.32. Training	*§ 1181a.32. Training* This proposed section mirrors the current §	**Comment: how restrictive will the DOH on approval of CE training**

	1181.32 (relating to training), except for revising a citation in subsection (a) to refer to this proposed chapter. This proposed section specifies those individuals who must complete a 4-hour training course prescribed by the Department and the requirements of that training course. Further, this proposed section provides that completion of the training course qualifies as continuing education credits by certain medical boards, and that individuals who completed the training course must submit documentation to that effect to the Department. Finally, this proposed section provides that the Department will provide on its web site a list of approved training providers.	**providers? Is there a process for approval?**
§ 1191a.28. Identification cards	*§ 1191a.28. Identification cards* This proposed section mirrors the current § 1191.28 (relating to identification cards), with one exception, as detailed as follows. This proposed section provides that the Department will issue identification cards as soon as practicable, and requires that the card contain certain delineated information, including a photograph of the cardholder. Subsection (c) provides that the Department will not require a photograph if the applicant submits a statement that a photograph cannot be provided due to the applicant's religious beliefs. Further, this proposed section outlines the circumstances under which an identification card issued to a patient or caregiver will expire. This proposed section omits the requirement in current subsection (f) that cardholders apply for a replacement card within 10 business days of discovering the loss or defacement of the card, as this requirement has been moved to proposed § 1191a.24(b) (relating to cardholder responsibilities).	**Comment: I am not familiar with this religious issue. Is this equal to how we handle PA issued IDs or passports?**
§ 1191a.31. Obtaining medical marijuana products from a dispensary	*§ 1191a.31. Obtaining medical marijuana products from a dispensary* This proposed section mirrors the current § 1191.31 (relating to obtaining medical marijuana products from a dispensary), except for amending citations have been amended throughout this section to refer to proposed Chapters 1161a	**Comment: usually there are no restrictions. It is preferred to leave the selection of appropriate forms to the medical professionals that are actually working inside the dispensary to avoid recommendations that make no sense such as recommendations for products that do not exist in our PA program, which happens occasionally.**

	and 1181a (relating to practitioners; and dispensaries). This proposed section provides that a medical marijuana cardholder may only obtain medical marijuana products from a dispensary in accordance with proposed § 1161a.24 (relating to limitations on dispensing), and that the cardholder may only obtain medical marijuana products from a dispensary based on the recommendation provided in a valid patient certification that the dispensary may access through the electronic tracking system.	
§ 1211a.29. Practices and procedures of research programs, projects or studies	*§ 1211a.29. Practices and procedures of research programs, projects or studies* This proposed section mirrors the current § 1211.29 (relating to practices and procedures of research programs, projects or studies). This proposed section requires medical marijuana to be dispensed to a patient or caregiver as part of a research program in a form that conforms to the act or this proposed part. This proposed section further provides that medical marijuana may be dispensed from a clinical registrant directly to an ACRC in any form deemed safe by an IRB. This proposed section further provides requirements for research approval committees and IRBs, including (1) establishing policies and procedures, (2) reviewing research studies and (3) ensuring each research study addresses the issues specified in proposed subsection (e).	**Questions: are patients in the research programs still paying for the cannabis medicines or are the research projects funded in some other way? Are we seeing research on new forms of cannabis or is the research more on specific responses for various symptoms or conditions?**
§ 1211a.30. Approval or denial of an application for approval of a clinical registrant	*§ 1211a.30. Approval or denial of an application for approval of a clinical registrant* This proposed section mirrors the current § 1211.30 (relating to approval or denial of an application for approval of a clinical registrant), except for revising citations to refer to this and other proposed chapters. This proposed section provides that an applicant shall be an approved clinical registrant upon the Department's approval of an application under proposed § 1211a.27 (relating to application for approval of a clinical registrant). This proposed section further provides that the Department may deny the application if the applicant has disclosed prior payments to a certified ACRC. This proposed section also specifies	**Comment: I do not understand the context for this proposed regulation and the prohibited payment** **Comment: generally I am unfamiliar with the timelines and status of cannabis research in PA.**

	that prior to denying an application, the Department will issue written notice to the applicant and the applicant will have the opportunity to cure the prohibited payments by submitting to the Department a supplemental affidavit indicating that the certified ACRC or its affiliate has refunded to the applicant the prohibited payment. Further, this proposed section provides that an approved clinical registrant will have the same rights and obligations as a grower/processor or dispensary permittee, and a clinical registrant's dispensary and grower/processor permits will expire upon expiration, revocation or nonrenewal of the clinical registrant's approval.	
§ 1211a.33. Dispensing and tracking medical marijuana products	*§ 1211a.33. Dispensing and tracking medical marijuana products* This proposed section mirrors the current § 1211.33 (relating to dispensing and tracking medical marijuana products), except for revising a citation to refer to proposed Chapter 1161a (relation to dispensaries). This proposed section provides that the dispensary of an approved clinical registrant shall enter information into the electronic tracking system as required by the Department identifying patients who are enrolled in an approved research program or research study, in addition to entering information about medical marijuana products dispensed to all patients and caregivers.	**Comment: where is this to be documented in MJ Freeway? Is this happening already?**
§ 1211a.36. Sale or exchange	*§ 1211a.36. Sale or exchange* This proposed section mirrors the current § 1211.36 (relating to sale or exchange), except for revising a citation to refer to this proposed chapter. This proposed section outlines the items a grower/processor of a clinical registrant may sell or exchange with another grower/processor and provides that a grower/processor of a clinical registrant may only sell its medical marijuana products to its own dispensary or to a dispensary owned by another clinical registrant. This proposed section further provides that an approved clinical registrant may petition the Department to sell its medical marijuana products to a dispensary in the commercial	**Comment: it seems there may be issues with research if the GP is unable to provide a consistent product or access to a product on a consistent basis. We see this in the dispensary in general already. Patients are frustrated when their tincture that worked so well last time is no longer available and may never be created again.** **Comment: is this suggesting that the new proposal is for the dispensary connected to the research program to no longer have exclusive access to the products from the GP participating in the research program?**

	market and specifies that the petition must include the report required by proposed § 1211a.35 (relating to reporting requirements).	
§ 1230a.39. Timeliness of Notice of Appeal	*§ 1230a.39. Timeliness of Notice of Appeal* This proposed section amends the current § 1230.39 (relating to timeliness of Notice of Appeal), as detailed as follows. This proposed section provides that the timeliness of a Notice of Appeal is measured from the mailing date of the written notice of the action, and an untimely filed Notice of Appeal may be deemed an admission or be dismissed with prejudice. This proposed section further provides that the Department may file an answer and new matter to a Notice of Appeal within 30 days of service of the Notice, but is not required to do so. This proposed section proposes two amendments. First, proposed subsection (a) provides that the timeliness of an appeal will be measured from the mailing date of the written notice of the action instead of the date the appellant receives the written notice, as specified in the current subsection (a). This proposed amendment removes ambiguity relating to timeliness of appeals and removes the possibility for differing time periods for appeal. Second, proposed subsection (b) provides that an untimely filed Notice of Appeal may be deemed an admission or may be dismissed by the Department, instead of the language in the current § 1230.39 that one's "failure to file" a timely Notice of Appeal results in the same. This proposed amendment is a technical clarification. This proposed section also provides that proposed subsection (a) supersedes 1 Pa. Code §§ 35.5—35.7, 35.20 and 35.35 (relating to informal complaints; appeals from actions of the staff; and answers to complaints and petitions).	**Comment: is there a timeline or is it unlimited now?** **Comment: there have been some issues with US MAIL and delays during the pandemic that may impact timed communications via US MAIL.**
§ 1230a.46. Entry of default judgment	*§ 1230a.46. Entry of default judgment* This proposed section mirrors the current § 1230.46 (relating to entry of default judgment). This proposed section provides	**Comment: it was my impression that there was no prescribing of medical cannabis since it is still federally illegal.** **Is it different within the research context?**

	that the Department, on motion of the Office, may enter default judgment against the respondent for failure to file within the required time an answer to an Order to Show Cause, order or other petition, to which the respondent may answer and have an opportunity to be heard; default judgment may not be granted prior to the hearing and the filing of an answer. C. *Affected Persons* Medical marijuana applicants, patients and their caregivers, as well as grower/processor and dispensary permittees and approved labs, will be required to comply with the provisions in this proposed rulemaking. Additionally, those individuals or entities that have not yet been issued a permit to receive, dispense or prescribe medical marijuana as well as successful future applicants will be required to comply with the provisions contained in this proposed rulemaking.	**Or is this for a different context.** **I thought the role of the physician was to say if the patient qualifies with a certifying condition and the role of the pharmacist was to assist the patient with information to make good choices and safely optimize the regimens.**
§ 1141a.21. Definitions	*Medical marijuana*—Marijuana for certified medical use, limited to the following forms: (i) Pill. (ii) Oil. (iii) Topical forms, including gels, creams or ointments. (iv) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization. (v) Tincture. (vi) Liquid.	**Comment: generally these categories should be revised to include or match the actual forms available in our program.** **Instead of Pill, suggest: tablet, capsule, softgel.** **Instead of oil, suggest: disposable or cartridge containing cannabis oil for vaporization** **Instead of Liquid, suggest: solution, tincture for ingestion or sublingual absorption** **Add suppositories.** **This is being addressed already by the pharmacists in the Advisory Group to DOH.**